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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,197	10/26/2001	Martin J. Wensley	00014.01R	1701

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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06/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/057,197

Applicant(s)

WENSLEY ET AL.

Examiner

Darwin P. Erez

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,39-43,48,124-130 and 135-197 is/are pending in the application.
- 4a) Of the above claim(s) 39-43,156-168,174,176,178 and 180 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10,11,135-155,169-173,175,177,179 and 197 is/are allowed.
- 6) ☒ Claim(s) 48,124-130 and 181-196 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims 39-43, 156-168, 174, 176, 178 and 180 drawn to an invention nonelected with traverse in the reply filed on 6/23/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 48 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,146,915 to Montgomery.

Montgomery teaches a method of generating an aerosol comprising the steps of heating a physiologically active compound via heaters **32** to vaporize the compound within chamber **12**. The vapor generated by the heaters are then mixed with a carrier gas (col. 2, lines 8-10) to form a ratio of vapor to carrier gas when a stable concentration of particles in the gas is reached (the heater is energized first prior to opening the inlet for the carrier gas); and the mixed vapor is administered to patient. In the embodiment shown in Fig. 3, the vapor is inherently cooled by the carrier gas at outlet **4** because the carrier gas is at room temperature. The embodiment of Fig. 3 does not have any heaters in the passageways 6, 19, 26 and regulator 14.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 124-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,388,574 to Ingebrethsen in view of US 5,894,841 to Voges.

(claim 124) Ingebrethsen teaches a method of generating aerosol comprising the steps of depositing a physiologically active compound (the other ingredient can also provide pharmacological effects = physiologically active) onto a mesh screen carrier (col. 4, line 32); and heating the compound by passing a current across the carrier to vaporize the compound (col. 4, lines 21-33).

Ingebrethsen is silent with regards to the method comprising the step of mixing the vapor with the carrier gas in a ratio to form a desired particle size when a stable concentration of particles in the gas is reached. However, Voges teaches that the

droplet size of an aerosol delivered to a patient is a function of the carrier gas pressure and velocity (col. 1, lines 43-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Ingebrethsen to include the step of mixing the resulting vapor with a carrier gas in a ratio to form a desired particle size since Voges teaches that it is well known in the art to control the particle size since the particle size is a function of the delivered pressure and velocity of the carrier gas, i.e., controlling the pressure and velocity of the carrier gas will alter the ratio of vapor to carrier gas. Furthermore, constant application of the same pressure and velocity of the carrier gas would produce aerosol with the same particle size, thus producing a stable concentration (inherent via the function of the pressure and velocity of the carrier gas in relation to the vapor).

(claims 125-127) Ingebrethsen teaches that the mesh can vary in size and configuration (col. 4, lines 29-30). Therefore, it would have been obvious to one of ordinary skill in the art to provide a single mesh screen or a plurality of mesh screens, or a mesh screen having 200 mesh, because Ingebrethsen teaches that any mesh screen configuration is usable in his invention. Thus, choosing a specific number of mesh screens would be a mere obvious design choice to one of ordinary skill in the art since either configuration would provide the same function of providing heat.

(claim 128) Ingebrethsen discloses a battery power source but is silent with regards to a capacitor power source. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a capacitor power

Art Unit: 3731

source since the examiner takes Official Notice of the equivalence of a battery power source and the capacitor power source for their use as a source of energy in the art and that the selection of any of these known equivalents would be within the level of ordinary skill in the art.

(claim 129 and 130) Ingebrethsen discloses the claimed invention except for the current being passed for the recited period of time. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to pass current for the recited period of time, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

7. Claims 181-186 and 188-196 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery, as applied to claim 48 in view of Voges.

(claim 181) Montgomery discloses all the limitations of the claims, except for the step of controlling the ratio of the vapor to gas by regulating the flow of said gas.

However, it is inherent to one of ordinary skill in the art that the ratio of vapor to gas is directly related to either the amount of vapor or to the amount of carrier gas.

Furthermore, Voges discloses that the droplet size of an aerosol delivered to a patient is a function of the carrier gas pressure and velocity (col. 1, lines 43-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the flow of gas in order to arrive at a desired droplet size for the aerosol.

(claims 182 and 183) The above combination is silent with regards to specifically controlling the ratio of vapor to gas via the rate of vaporization by controlling the energy transferred to the compound during the heating step. However, this would have been an obvious step to one of ordinary skill in the art at the time the invention was made since Montgomery teaches an adjustable heater (col. 3, lines 26-27), which would inherently regulate the rate of vaporization.

(claim 184) Montgomery discloses depositing the compound into a substrate (the vaporizing chamber 12) prior to heating.

(claim 185) Montgomery discloses passing gas across the surface of the vaporized compound at the outlet 4.

(claim 186) Montgomery discloses all the limitations of the claim except for the particle size. However, Voges discloses that particle sizes in the range of about 1-3 microns is the preferred size for respiratory treatment (col. 5, lines 3-4 of Voges). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the particle size in the range of about 1-3 microns because such particle size is usable for respiratory treatments.

(claim 188) Montgomery discloses the use of air as carrier gas (col. 1, line 9).

(claim 189) Montgomery discloses all the limitations of the claim except for the cited compounds. However, Voges discloses nicotine to be a desired vaporized compound (col. 3, line 2 of Voges). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vaporize any volatile

compound in the device of Montgomery, including nicotine, since the use of a specific compound is merely dependent upon the intended therapy.

(claims 190-191) The above combination discloses the claimed invention except for the recited range of time. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

(claim 192) The deposition of the compound to the substrate (the vaporizing chamber) is viewed as a thin film layer.

(claim 193) A thermal energy gradient is provided in multiple prong locations about the heater **32**.

(claim 194) The heating-vaporizing zone is viewed as a restricted cross-sectional area. It is noted that this limitation does not positively recite any structural elements.

(claims 195-196) The heaters are of the resistance type, wherein the two prongs is viewed as being heated sequentially (one gets hotter before the other).

8. Claim 187 is rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 5,874,841 to Weers et al.

The above combination of Montgomery/Voges is silent with regards to the particle size in the range of 10 nm to 100 nm. Weers teaches that is known in the respiratory art to have particle sizes in the range of 10 nm to 100 nm (col. 5, line 6).

Art Unit: 3731

Therefore, it would have been obvious to one of ordinary art at the time the invention was made to modify the steps taught by the above combination to include the particle size range of 10 to 100 nm since Weers teaches that the recited range is known in the art and would be dependent upon the intended therapy.

Allowable Subject Matter

9. Claims 10, 11, 135-155, 169-173, 175, 177, 179 and 197 are allowed.

Response to Arguments

10. Applicant's arguments filed 3/21/07 have been fully considered but they are not persuasive.

With regards to the Montgomery reference, the applicant argued that Montgomery fails to teach the limitation of cooling the resulting vapor by mixing the vapor with a gas. The applicant relies on the embodiment shown in Fig. 4 and col. 4, lines 19-25. However, it is noted that the embodiment shown in Fig. 3 does not recite any heaters in the passageways 6, 19, 26 and regulator 14. Therefore, the vaporized gas coming out of the vaporizing chamber will inherently be cooled by the carrier gas that is provided at room temperature (no heater).

With regards to the Ingebrethsen reference, the applicant argued that Ingebrethsen fails to teach an active compound that is vaporized. However, as noted in the rejections above, Ingebrethsen discloses that the either the active ingredient or the "other ingredient" can have pharmacological effects (col. 7, lines 33-35). Ingebrethsen discloses the "other ingredient" to be vaporized.

With regards to the rejection for claim 128, the Examiner used Official Notice stating that the use of either a capacitor and battery source is common knowledge. Since the applicant failed to traverse this rejection, the common knowledge statement is taken to be admitted prior art. See MPEP 2144.03(C).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Darwin P. Erez
Examiner
Art Unit 3731

de


(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

5/29/07